

Message Text

UNCLASSIFIED

PAGE 01 STATE 036564
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 /025 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/WE:BMCKINLEY(INFO)

-----171943 082544 /47

P 171912Z FEB 77
FM SECSTATE WASHDC
TO AMCONSUL MILAN PRIORITY
AMEMBASSY ROME

UNCLAS STATE 036564

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, IT

SUBJECT: NON-SPECIFIC IN-VITRO BIOLOGICAL DIAGNOSTIC
PRODUCT (RECALL B-008-7)

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

PRODUCT INVOLVED:

METABOLIC ANTI-RH TYPING SERUM, ANTI-RHO (ANTI-D), 5ML AND
10ML VIALS. PRODUCT IS USED AS A TYPING SERUM.

PRODUCT IDENTIFICATION:

LOT M22D (MASTER POOL AND PACKAGING NUMBER) AND ALL SUB-
SEQUENT PACKAGING LOTS (E.G. M22D2, M22D3, ETC.).

MANUFACTURER/RECALLING FIRM:

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METABOLIC, INC.
4520 YOAKUM BLVD.
HOUSTON, TEXAS 77006

2. REASON FOR RECALL RECOMMENDATION:

SAMPLE ANALYSIS BY FDA OF ANTI-RH SERUM ANTI-RHO (ANTI-

D) LOT M22D INDICATED THAT THE PRODUCT IS NON-SPECIFIC WHEN TESTED AGAINST SOME RHO(D) NEGATIVE CELLS. THIS FACT CAUSES THE PRODUCT TO BE ADULTERATED AND MISBRANDED UNDER THE F.D. AND C. ACT.

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE ITALFARMACO, S.P.A.; ZLE FURIO TESTI, 330; 20106 MILAN, ITALY TO ASCERTAIN WHETHER THEY HAVE RECEIVED LETTER DATED 1 FEBRUARY 1977 REGARDING THIS RECALL. THE RECALL LETTER STATES IN PART AS FOLLOWS: "THIS IS TO NOTIFY YOU THAT ANTI-RH TYPING SERUM, ANTI-RHO (ANTI D), LOTS M22D, M22D2 AND M22D3 CONTAIN ANTI BGA. AGGLUTINATION MAY OCCUR WITH CERTAIN RED BLOOD CELLS POSITIVE FOR THE BG ANTIGEN WHEN TESTED BY THE INDIRECT ANTIGLOBULIN METHOD DUE TO THE PRESENCE OF ANTI BGA. IF SUCH AGGLUTINATION IS SUSPECTED, RETEST WITH ANOTHER LOT OF ANTI-RH TYPING SERUM, ANTI-RHO (ANTI D)". ANY QUESTIONS FOREIGN CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO THE FIRM.
HARTMAN

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: BLOOD, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 17-Feb-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE036564
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770057-0580
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770230/aaaabazg.tel
Line Count: 82
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 8f9317c5-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 26-Nov-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3293160
Secure: OPEN
Status: NATIVE
Subject: NON-SPECIFIC IN-VITRO BIOLOGICAL DIAGNOSTIC PRODUCT (RECALL B-008-7)
TAGS: OGEN, ETRD, EIND, TBIO, IT
To: MILAN ROME
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/8f9317c5-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
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